

REMARKS

The above-referenced application has been reviewed in light of the Office Action mailed August 3, 2005. By the present amendment, the Applicant has amended claims 2, 8, and 9. It is respectfully submitted that the claims pending in the application do not introduce new subject matter, are fully supported by the specification, and are patentable over the prior art. Prompt and favorable consideration of these claims is earnestly sought.

The Office Action rejected claims 2-5, 7-9, and 11-13 under 35 U.S.C. § 112, first and second paragraphs. In the interests of furthering prosecution, the Applicant has amended claims 2, 8, and 9 to remove the term "slidably." Therefore, it is respectfully submitted that claims 2-5, 7-9, and 11-13 satisfy the requirements of 35 U.S.C. § 112 and that the rejection of the Office Action has been overcome.

The Office Action rejected claims 2, 5, 7-9, and 13 under 35 U.S.C. § 103 (a) as being unpatentable over U.S. Patent No. 4,655,746 to Daniels et al. (the '746 patent) in view of U.S. Patent No. 5,180,367 to Kontos et al. (the '367 patent). According to the Office Action, the '746 patent discloses a first tubular member 68 having an open proximal end, a first inflatable member 72, a second tubular member 16 having open proximal and distal ends defining a bore 18 therethrough and a second inflatable member 30. The Office Action acknowledged that the '746 patent is deficient in that it fails to disclose the first inflatable member 72 and the first tubular member 68 having an open distal end and also acknowledged that guide wire 74 plugs the distal end of the first inflatable member 72. The Office Action stated that the '367 patent discloses that the tubular member of the inner, pilot balloon can have an open distal end so that it can slidably

receive the guide wire and that it would have been obvious to make the distal end of the first inflatable member 72 and the first tubular member 68 of the '746 patent open as disclosed in the '367 patent.

As presently amended, claim 2 recites, *inter alia*, an apparatus including a first inflatable member having a first aperture, a second inflatable member having a second aperture wherein "the first aperture and the first bore being configured and dimensioned for receiving a surgical instrument therethrough."

The '746 patent relates to a catheter device for delivering fluids to a target region in a vessel of a patient by isolating the target region using two inflatable balloons. Specifically, the '746 patent discloses that a guide wire 74 is disposed in the interior of inflatable balloon 72 and is attached to a flexible spring 76 at the distal end of the inflatable balloon. As acknowledged in the Office Action, the distal end of the inflatable balloon 72 is plugged by guide wire 74 and more specifically by a flexible spring 76 (see Figure 5 reproduced below). According to the '746 patent, the guide wire 74 is used to guide the tube 68 and inflatable balloon 72 into a blood vessel (the '746 patent at Column 6, lines 28-50) through tube 16. In addition, the '746 patent discloses (Column 4, lines 57-59) that the guide wire is "securely anchored to the distal end of the tube 68 but can otherwise twist or rotate with respect to the tube along the tube's length." Further still, as evidenced by Figure 5, the flexible spring 76 functions as a pressure boundary that allows the inflatable balloon 72 to inflate upon the introduction of a pressurized fluid. The '367 patent discloses a tubular member having an open distal end so that a guide wire may extend through the open distal end.

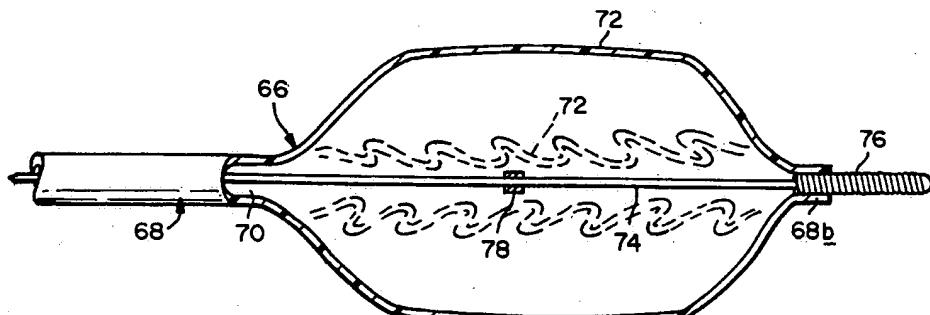


FIG. 5.

Modifying the device disclosed in the '746 patent to have an open distal end as disclosed in the '367 patent as suggested in the Office Action would be contrary to the disclosure of the '746 patent and would render the disclosed device inoperable for its stated purpose. The '746 patent clearly discloses an inflatable balloon having a closed distal end (i.e. the flexible spring 76). Moreover, as discussed hereinabove, the closed distal end of the inflatable balloon 72 has specific purposes that are essential to the operation of the disclosed device and is required by the disclosed device. Providing an open distal end as disclosed in the '367 patent, and as suggested in the Office Action, would render the device of the '746 patent incapable of performing its stated purposes. Replacing the closed distal end (i.e. the flexible spring 76) of the inflatable balloon 72 with an open distal end would remove a pressure boundary of the inflatable balloon 72 and prevent the inflatable balloon from retaining a pressurized fluid thereby defeating one of the '746 patent's stated purposes of (see Column 2, lines 35-47):

The catheter device is intended for use in transferring fluid material to or from a selected-length segment of a vessel. In practicing the method of the invention, the first catheter is threaded into the vessel of interest until the associated balloon is positioned adjacent one end of the vessel [sic] segment. As part of the positioning procedure, the catheter may be used to deliver a contrast agent for

purposes of tissue imaging. The second catheter is then threaded through the first catheter and into the vessel until its balloon is positioned adjacent the other end of the segment. Inflating the two balloons isolates the vessel segment. Fluid is then transferred through the device into or out of the isolated segment.

Further still, removing the attachment point for the guide wire to the inflatable balloon would render the device of the '746 patent incapable of being maneuvered from the proximal end of the device. According to the '746 patent, the guide wire is connected to the flexible spring at the distal end of the inflatable balloon so that the inflatable balloon is positionable and rotatable from the proximal end of the device (the '746 patent at Column 6, lines 28-50). Removing the flexible spring 76 to create an open distal end as disclosed in the '367 patent, and as suggested in the Office Action, would further eviscerate the disclosed device. An open distal end (i.e. removing flexible spring 76) would disconnect the inflatable balloon 72 from the guide wire 74, thereby preventing control over the balloon's movement from the proximal end of the device as disclosed in the '746 patent. This is contrary to the disclosure of the '746 patent since the '746 patent discloses (Column 4, lines 57-59) that the guide wire is "securely anchored to the distal end of the tube 68 but can otherwise twist or rotate with respect to the tube along the tube's length." In addition, the '746 patent states (Column 5, lines 2-5) that the "guide wire and rotating means are also referred to herein collectively as means for guiding the distal end of the second catheter within the first-catheter channel, and in the region distal thereto."

Therefore, providing an open distal end as disclosed in the '367 patent to the device disclosed in the '746 patent does not result in a device having, *inter alia*, a first inflatable member having a first aperture, a second inflatable member having a second aperture wherein

"the first aperture and the first bore being configured and dimensioned for receiving a surgical instrument therethrough" as recited in amended claim 2. It is respectfully submitted that amended claim 2 is not suggested by the combination of the '746 patent in view of the '367 patent and the rejection of the Office Action has been overcome. Claims 5, 7-9, and 13 depend directly or indirectly from amended claim 2 and it is respectfully submitted that the rejection of these claims has been overcome as well.

Claims 3 and 4 were rejected in the Office Action under 35 U.S.C. § 103 (a) as being unpatentable over the '746 patent in view of the '367 patent and further in view of U.S. Patent No. 4,981,478 to Evard et al (the '478 patent). The Office Action stated that the '746 patent fails to disclose an inner member defining an annular space with the first tubular member, but that the '478 patent discloses that a balloon catheter can be constructed with an inner tubular member 13 and an outer tubular member 11 with an annular space therebetween. Further still, the Office Action stated that it would have been obvious to construct the first tubular member of the '746 patent to so it would also include this feature.

Claims 3 and 4 depend directly or indirectly from amended claim 2. As discussed hereinabove, the device recited in amended claim 2 is not suggested by the combination of the '746 patent in view of the '367 patent. Adding the annular space between inner and outer tubular members as disclosed in the '478 patent, as suggested by the Office Action, does not overcome the deficiencies of the '746 patent in view of the '367 patent and does not result in a device having, *inter alia*, a first inflatable member having a first aperture, a second inflatable member having a second aperture wherein "the first aperture and the first bore being configured and

dimensioned for receiving a surgical instrument therethrough" as recited in amended claim 2.

Therefore, it is respectfully submitted that claims 3 and 4 are not suggested by the combination of the '746 patent in view of the '367 patent and further in view of the '478 patent, and the rejection of the Office Action has been overcome.

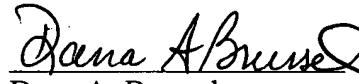
Claims 11 and 12 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over the '746 patent in view of the '367 patent and further in view of U.S. Patent No. 4,690,140 to Mecca (the '140 patent). According to the Office Action, the distal end of the first tubular member 68 of the '746 patent, as modified hereinabove to include the asserted advantages of the '367 patent, would inherently be capable of receiving an endoscope or a laparoscopic instrument.

Claims 11 and 12 depend directly from amended claim 2. As discussed hereinabove, the device recited in amended claim 2 is not suggested by the combination of the '746 patent in view of the '367 patent. Adding the surgical instrument as disclosed in the '140 patent, as suggested by the Office Action, does not overcome the deficiencies of the '746 patent in view of the '367 patent and does not result in a device having, *inter alia*, a first inflatable member having a first aperture, a second inflatable member having a second aperture wherein "the first aperture and the first bore being configured and dimensioned for receiving a surgical instrument therethrough" as recited in amended claim 2. Therefore, it is respectfully submitted that claims 11 and 12 are not suggested by the combination of the '746 patent in view of the '367 patent and further in view of the '140 patent, and the rejection of the Office Action has been overcome.

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In view of the foregoing amendments and remarks, it is respectfully submitted that all claims pending in the application, namely claims 2-5, 7-9, and 11-13, are in condition for allowance. Should the Examiner desire a telephonic interview to resolve any outstanding matters, he is sincerely invited to contact the undersigned at (631) 501-5713.

Respectfully submitted,



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